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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/483,184 | 01/14/2000 | Ruth W. Craig | DART1110-1 | 8067 |

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[REDACTED] EXAMINER

CANELLA, KAREN A

[REDACTED] ART UNIT

[REDACTED] PAPER NUMBER

1642

DATE MAILED: 01/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

| | | |
|--------------------------------------|------------------------------------|---|
| Application No. 09/483,184 | Applicant(s) Craig et al |  |
| Examiner Karen Canella | Art Unit 1642 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 months MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on _____.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-21 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-21 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) Notice of References Cited (PTO-892)

18) Interview Summary (PTO-413) Paper No(s). _____

16) Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) Notice of Informal Patent Application (PTO-152)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

20) Other: _____

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Response to Amendment

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.
2. Claims 22-81 have been canceled. Claims 1-21 are pending and under consideration.
3. The rejection of claims 1-9 under 35 U.S.C. 101, because the claimed invention is not supported by either a specific, substantial asserted utility or a well established utility, is maintained for reasons of record.
4. The rejection of claims 1-9 under 35 U.S.C. 112, first paragraph is also maintained, as one of skill in the art would not know how to use the claimed products which lack utility.
5. Claims 1-9 are drawn to the Mcl-1 gene regulatory region. Applicant argues that the specification discloses that an Mcl-1 gene regulatory region can be used as a tool for identifying an agent that can modulate the expression of a nucleotide operatively linked to said regulatory element. Applicants submit that such a utility is well known because it is routine in the art to use newly isolated gene regulatory elements to identify agents that regulate expression from the element, or co-express a reporter gene. Applicant argues that this is a specific activity as only the disclosed regulatory element can be used for such a purpose; substantial because Mcl-1 gene expression is linked with apoptosis, and credible because such uses and methods as disclosed for the Mcl-1 regulatory element have been practiced with other gene regulatory elements. This has been considered but not found persuasive. Although it is routine in the art to use newly isolated regulatory elements to identify agents that regulate gene expression from the element, this is not a patentable utility as it constitutes further experimentation regarding the activation of the regulatory element. Further, the Mcl-1 gene product is linked with the delay of apoptosis, not the promoter for the Mcl-1 gene and as such, the Mcl-1 gene product can be recombinantly

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expressed from numerous promoters. Therefore the utility attributed to the Mcl-1 gene regulatory region is neither specific nor substantial.

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New Claim Rejection

6. Claim 10-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 10-21 are drawn to nucleic acids encoding the Mcl-1 polypeptide. As stated in the previous Office action, the specification provides no objective evidence that induction of the Mcl-1 polypeptide in neurons would be sufficient to prevent the neurons from undergoing apoptosis, as Mcl-1 is a protein found in hematopoietic cells, which are biochemically distinct from neurons, potentially rendering the Mcl-1 protein as useless in the context of a neuronal cell. Further, the specification provides no objective evidence that the administration of SEQ ID NO:3 to patients suffering from cancer would be effective in inducing apoptosis of cancer cells. Cancer is a complex and multiple step process that proceeds by the acquisition of successive genetic insults (A. Hagemeijer, Leukemia, 1992, Vol. 6, Suppl. 4, pp. 16-18) resulting in accumulation of mutant forms of proteins and disruption of growth control (H. Varmus, Oncogenes and the Molecular Origins of Cancer, Weinburg ed., 1989, p. 36, last paragraph). Thus the malignant phenotype is subject to variables beyond the expression of a single protein such as Mcl-1. Therefore without objective evidence in the specification, one of skill in the art cannot assume the administration of a dominant negative truncation mutant of Mcl-1 would function by inducing apoptosis in cancer cells. One of skill in the art would be subject to undue experimentation without reasonable expectation of success in order to use the claimed polynucleotides.

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Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.
Patent Examiner, Group 1642
December 31, 2001

[Handwritten signature of Karen A. Canella]
KAREN A. CANELLA
PATENT EXAMINER
DECEMBER 31, 2001